

Report on the Conference of National Tuberculosis Reference Laboratories from Central and East European Countries

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Congress Report

The conference was organized by INSTAND/WHO Collaborating Centre for Quality Assurance and Standardization in Laboratory Medicine, Duesseldorf/Germany, the European Supranational Reference Laboratory (SRL) for Quality Assurance of Tuberculosis, Borstel/Germany and the Romanian Tuberculosis National Reference Laboratory Cluj-Napoca/Romania and was held from April 28 to 30, 2011 in Cluj-Napoca/Romania.

The SRL in Germany was nominated by WHO. ECDC launched a European network on Tuberculosis (ERLN-TB) in 2010. The SRL in Borstel is the representative for Germany in this network. It works closely together with INSTAND/WHO in Duesseldorf/Germany concerning external quality assurance (QA) of laboratory diagnosis of tuberculosis in Europe.

Tuberculosis is still a major health problem in the world. Every year about 8.8 million new active cases and nearly 2 million deaths world wide – 5000 every day – were registered. One third of the world's population has latent TB infections, which has high significance in perspective to HIV. Another growing problem is the multi-drug resistance of the bacteria [1].

The collapse of the Soviet System in many countries lead to fundamental social changes. The destruction of health facilities, the social problems, the financial situation, the increase of HIV infection, the backwardness in therapy and diagnostic lead to an enormous increase in TB cases. The proportion of laboratory-confirmed TB cases was still extremely low in 2009 in the European Union countries and ECDC supervision area. Only seven EU/EEA member states achieved the target of $\geq 80\%$ culture confirmation among new pulmonary cases, as defined in the EU monitoring framework (http://ecdc.europa.eu/en/publications/Publications/101111_SPR_Progressing_towards_TB_elimination.pdf).

In 2008 Romania was one of the European countries with the tuberculosis incidence over 101/100,000 inhabitants (<http://ecdc.europa.eu/>), but in 2010 it decreased to 90.5/100,000 inhabitants. Since 2002, the incidence rate decreased in Romania with 36.3%, from 142.2/100,000 to 90.5/100,000 in 2010 (30,984 TB cases to 19,395 TB cases, respectively) (Elmira Ibraim, INSTAND Conference Cluj, April 2011, personal presentation), due to TB control activities of both pneumologists and microbiologists.

These facts and also the long lasting relation to the colleagues working for QA in Romania made up the decision to organize this meeting in Cluj/Romania.

The basis for a successful therapy and control is an optimal laboratory diagnosis for the detection of the TB bacterium. The heads from nine National Reference Laboratories from Central- and East-European countries where invited to this conference. The idea was that these laboratories may have or get a voice in the policy of their ministries of health and that they establish a highly effective and quality assured standard of laboratory diagnosis of TB.

A statement of the situation of TB laboratory diagnosis in the invited countries as well as the exchange of experiences can be fruitful for the improvement of the control of this important disease. The aim of this conference was also to work out a consensus paper about the state of the art of quality assured laboratory diagnosis of TB as a part of the nation-wide control programs in the different countries.

At first Dr. Alexandra Clarici from the European Centre for Disease Prevention and Control (ECDC) in Stockholm/Sweden gave an introduction on "Actual TB situation in sight of ECDC".

The following Heads of National TB Reference Laboratories as official representatives gave their country reports:

- Dr. Bachiyiska, Elizabeta – Bulgaria
- Dr. Barbova, Anna – Ukraine
- Dr. Crudu, Valeriu – Moldavia
- Dr. Homorodean, Daniela – Romania
- Dr. Katalinic-Jankovic, Vera – Croatia
- Dr. Ruesch-Gerdes, Sabine – Germany
- Dr. Tahirli, Rasim – Azerbaijan
- Dr. Zolnir, Manca – Slovenia
- Prof. Dr. Zwolska – Zofia, Poland

The presentations were scheduled into the following topics:

- Network from Ministry of Health to Peripheral Laboratories
- Laboratory Techniques (Microscopy, Culture, Drug Susceptibility Testing, Molecular based Methods, Identification of Mycobacterium)
- External Quality Assurance
- Needs for Improvement of Laboratories (Techniques, Equipment, Rooms, Training, Bio-safety)
- Accreditation
- Funding

Beside these official representatives colleagues from the Romanian TB Laboratory Working Group and from further countries were taking part in this meeting.

The country reports were discussed by the auditorium in detail and gave the basis for the following consensus paper:

Findings and Consensus

1. *A National Reference Laboratory with the official status from the Ministry of Health (MoH) exists in nearly all countries, but not all laboratories have enough power within the whole TB program.*

All countries without the official status can perhaps get a letter from their Supra-National Reference Laboratories (SRLs) with the content that it will be necessary to have the acceptance from the MoH, important for different co-operations etc.

The main criteria for a NRL are a permanent functional laboratory, which is able to use routinely conventional and new diagnostic tools for primary isolation, differentiation, and drug susceptibility testing. The NRL should offer external quality and training programs for the regional laboratories and must be able to retest strains with a drug resistance detected by the regional laboratories. Additionally the NRL should be involved in implementation of new techniques to be used in the other laboratories and of course has to be involved in all topics regarding tuberculosis in their country.

The NRL should have enough staff to fulfil the criteria of a NRL.

2. *A laboratory network is established in nearly all countries.*

A network has to be established with clear tasks what the laboratories can and have to do. Additional a

network for external quality control has to be implemented, not only for smear microscopy but for Drug Sensitivity Testing (DST), too.

3. *All NRLs are linked to a SRL.*

A co-operation agreement between the NRL and the SRL has to be signed by both partners.

4. *A good co-operation between the civilian and the penitentiary system does not exist in all countries.*

It is very important for the whole TB program to have a good co-operation between the MoH and Ministry of Justice (MoJ). For example: the treatment for prisoners with an active tuberculosis has to be continued in the civilian section after the patients are released.

5. *Not all laboratories have an infection control program implemented and can't work under adequate biosafety conditions.*

All laboratories must have an infection control program implemented and must have established a safe workflow. All equipment has to be maintained routinely, ideally by a trained national person.

6. *Drug susceptibility testing is not performed for all patients in some countries.*

Results of DST have to be available for all patients, important not only for a proper treatment regimen, but also for proper accommodation in a hospital to interrupt transmission chain of resistant strains. The obligation to perform DST from all positive cultures should be incorporated in the national TB programme (this can be not the decision of the clinicians). Strict recommendations have to be implemented and followed by the laboratories.

7. *New rapid techniques are not used in all countries.*

To decrease the number of MDR/XDR tuberculosis, new methods for the rapid detection of resistant tuberculosis cases have to be used worldwide. There are two methods for the rapid detection of MDR, recommended by WHO, available: the LPA and the GeneXpert. Additionally before performing DST in solid or liquid media all strains have to be differentiated properly to make sure that a detected resistance belongs to an *M. tuberculosis* strain and not to a non-tuberculosis mycobacteria. The differentiation with biochemical tests is not sufficient today. Rapid, sensitive, and specific methods are already well established and can be used in all level of laboratories performing cultures.

All countries should have clear recommendations which techniques have to be performed and additional all laboratories have to follow strictly Standard Operating Procedures (SOPs) and national and international guidelines, which should be in place everywhere.

8. *A proper working recording and reporting system is in place in all the meeting attending participants countries.*

9. *Strains and specimens are not stored in all laboratories properly.*

All specimens should be stored at least till the end of the investigation ideally in a refrigerator. All strains should be stored in a freezer with glycerol.

10. *Three questions arised during the meeting:*

a. Should we report the mutations, responsible for a drug resistance?

The agreement within the group was to report only the mutations if it will be helpful for the clinicians and if the clinicians have been trained in interpretation of the results.

b. Should we recommend molecular based methods, like spoligotyping, RFLP or MIRU?

For the improvement of the infection control the knowledge about the transmission rate can be very helpful for the fight against tuberculosis. Depending on laboratory capacity and money, a routinely used fingerprinting of resistant or all strains is recommended.

c. What can the countries do in the future if money from international organizations are not available? It will be absolutely important to plan a national budget regarding laboratory issues without international money.

The conference gave an impression of the situation of TB reference laboratories in different countries. The political significance as well as the financial situation of the NRLs must be improved. New laboratory techniques should be introduced. Quality Assurance on an international level is well established. Bio-safety is very essential and must be existing in each laboratory. Infection control programs have to be in place in all TB laboratories.

The SRLs, INSTAND/WHO as well as the ECDC are willing to support the NRLs, but financial assistance is the business of the countries themselves.

The organizers and the participants of the meeting think that this fruitful conference was a significant step forward

in improvement of laboratory diagnosis of tuberculosis in their countries. On the next assembly the latest improvement, the handicaps, as well as the situation in the level under the NRLs, should be discussed.

References

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